

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants: Damien CAMELOT, *et al.*

Title: ENCAPSULATED CRYSTALLINE LACTIC ACID

Appl. No.: 10/631,831

Filing Date: 08/01/2003

Examiner: Helen F. Pratt

Art Unit: 1761

Confirmation Number: 1704

**BRIEF ON APPEAL**

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Sir:

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**I. REAL PARTY IN INTEREST**

The real party in interest is Purac Biochem B.V.

**II. RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any related appeal or interferences.

**III. STATUS OF CLAIMS**

Claim 6 is canceled and claims 1-27 are pending. Claim 17 is withdrawn. Hence, claims 1-5, 7-16 and 18-27 are under consideration, rejected, and appealed.

**IV. STATUS OF AMENDMENTS**

Appellants have made no amendments to the claims after the Final Office Action mailed March 29, 2007. All amendments have been entered.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

There are three independent claims on appeal, all of which are directed to a novel encapsulated particle comprising crystalline lactic acid and a wetting agent; and methods of using and preparing same. A concise explanation of the subject matter defined by these three independent claims is provided below.

**Claim 1:** Claim 1 is drawn to a “composition comprising an encapsulated particle comprising crystalline lactic acid and a wetting agent.”<sup>1</sup>

**Claim 15:** Claim 15 is directed to a method of preparing a food product comprising adding encapsulated crystalline lactic acid particles to the food product whereby “the color, flavor, or shelf-life of the food product is enhanced compared to a similar food

product prepared without adding lactic acid.”<sup>2</sup> The encapsulated crystalline lactic acid particles comprise crystalline lactic acid and a wetting agent.

**Claim 18:** Claim 18 is drawn to a method of preparing encapsulated crystalline lactic acid particles. The method comprises (a) preparing crystals of lactic acid; (b) treating the crystals with a wetting agent prior to or during encapsulation; and (c) coating the crystals with an encapsulating coating material.<sup>3</sup>

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Appellants present a single ground of rejection for consideration on appeal. Specifically, Appellants present for consideration the rejection of claims 1-5, 7-16 and 18-27 under 35 U.S.C. 103(a) as allegedly obvious over European Patent No. 0699392 to Chung, *et al.* (“Chung”) or U.S. Patent No. 6,153,236 to Wu, *et al.* (“Wu”) or U.S. Patent No. 4,537,784 Percel, *et al.* (“Percel”) in view of Borsook, H., *et al.*, “The Preparation of Crystalline Lactic Acid,” Kerckhoff Laboratories of Biological Scienecs, California Institute of Technology, Pasadena, CA, June 7, 1933, pages 449-460 (“Borsook”) and Schouten et al., “Low Temperature Crystal Structure and Molecular Conformation of L(+) Lactic Acid,” *J. Mol. Structure*, 323: 165-168 (1994) (“Schouten”).

## **VII. ARGUMENT**

Neither Chung, Wu, or Percel (the “primary references”) in view of Borsook and Schouten (the “secondary references”) renders the claimed invention obvious for at least two reasons. First, there is no *prima facie* case of obviousness because there is no motivation to

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<sup>1</sup> See Spec. at 4, lines 10-11.

<sup>2</sup> See Spec. at 5, lines 4-7.

<sup>3</sup> See Spec. at 5, lines 10-13.

combine the references. Moreover, given the disclosures of the primary references, one of skill in the art would have no reasonable expectation of success in obtaining the claimed invention following the collective teachings of the cited references. The entire rejection is based on the rationale that because Chung, Wu, and Percel suggests encapsulated lactic acid compositions, one of skill in the art would have found obvious to substitute crystalline lactic acid, for liquid lactic acid. Such reasoning runs afoul of explicit evidence to the contrary, and therefore cannot adequately support the obviousness rejection. Second, any *prima facie* case of obviousness has been rebutted by showing unexpected results. Indeed, the claimed invention provides an encapsulated particle comprising crystalline lactic acid and a wetting agent composition that provides a number of unexpected properties and advantages as compared to traditional encapsulated lactic acid compositions.

**A. The Examiner Has Failed to Establish a Prima Facie Case of Obviousness**

A *prima facie* case of obviousness requires three basic criteria to be met.<sup>4</sup> First, there must be some suggestion or motivation to modify the references or to combine reference teachings in such a way as to arrive at the claimed invention.<sup>5</sup> Second, one of skill in the art must have a reasonable expectation of success in combining or modifying the references in the way suggested.<sup>6</sup> Finally, the prior art references must teach or suggest all the claim limitations when combined.<sup>7</sup>

Here, there is no *prima facie* case of obviousness because the appealed rejection fails to satisfy at least two of the basic criteria. First, there is no suggestion or motivation to

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<sup>4</sup> See MPEP § 2142; see also *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ.2d 1438, 1442 (Fed. Cir. 1991).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

modify the references in the manner argued by the Examiner. Second, given the disclosures of the cited references, one of skill in the art would not have a reasonable expectation of success in modifying the references as suggested by Examiner. Thus, the obviousness rejection cannot be sustained.

#### **1. The Prior Art Lacks Motivation To Combine Chung, Wu, or Percel with Borsook and Schouten**

Chung, Wu and Percel disclose encapsulated particles (e.g., food acids and/or oils). None of these references, however, teach or disclose an encapsulated particle comprising *crystalline* lactic acid and a wetting agent. The Examiner appears to recognize this deficiency, at least with respect to Chung and Wu.<sup>8</sup> With respect to Percel as well, the Examiner appears to acknowledge that the reference does not expressly teach the use of crystalline lactic acid, but the Examiner alleges “the lactic acid is seen as being crystalline as it is anhydrous and if it is on a carrier no water is seen to make it not crystalline.”<sup>9</sup>

Appellants respectfully submit that the Examiner has improperly convoluted two scientific concepts in likening “crystalline” to “anhydrous.” *To wit*, “dry” or “powdered” lactic acid is not necessarily the equivalent of “crystalline” lactic acid. A substance is not rendered “crystalline” merely because it is anhydrous, and in fact, many crystalline substances, particularly those that are very hygroscopic such as crystalline lactic acid, can contain water.

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<sup>8</sup> Chung describes coating of various “leavening acid cores” with a “barrier material”. While four suitable organic acids are listed, notably, lactic acid is not mentioned. Page 4, 2<sup>nd</sup> paragraph. Similarly, at col. 4, lines 54-56, Wu explicitly states: “Lactic acid, *being a liquid*, is first applied to a carrier such as calcium lactate and converted to a dry solid form.” (Emphasis added.)

<sup>9</sup> Office Action mailed March 29, 2007 at 2.

In an attempt to cure this deficiency, the Examiner introduces Borsook and Schouten for the proposition that crystalline lactic acid particles are well known. However, a prior art reference must be considered in its entirety, including disclosures that teach away from the claims.<sup>10</sup> In fact, “[i]t is improper to combine references where the references teach away from their combination.”<sup>11</sup> Appellants respectfully submit that the present combination of references in the alleged *prima facie* case for obviousness does not heed this admonition.

Appellants have made clear that the mere existence of crystalline lactic acid in the art is not disputed. Rather, Appellants respectfully submit that the use of crystalline lactic acid for the claimed compositions and methods were heretofore unknown, unappreciated, and unobvious.

Percel, for example, sets forth the state of the art at the time the present invention was conceived: “Lactic acid in crystalline form is very deliquescent and when exposed to atmosphere quickly liquefies. It has thus been impossible to use crystalline lactic acid for meat acidulation.”<sup>12</sup> In view of the “impossibility” of encapsulating liquid lactic acid, the art taught that lactic acid had to be adsorbed onto a solid carrier (e.g., calcium lactate), which could then be processed. Accordingly, Percel teaches the use of *liquid* lactic acid sprayed onto a solid carrier.<sup>13</sup>

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<sup>10</sup> See MPEP § 2141.02(VI); see also *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

<sup>11</sup> See MPEP § 2145(X)(D)(2)

<sup>12</sup> Percel at col. 2, lines 13-16.

<sup>13</sup> *Id.* at col. 4, lines 5 – 27.

The remaining primary references are consistent with the disclosure of Percel. Wu teaches that “lactic acid, being a liquid, is first applied to a carrier such as calcium lactate and converted into a dry solid form.”<sup>14</sup> Chung describes coating of various “leavening acid cores” with a “barrier material.”<sup>15</sup> Most telling is that while four suitable organic acids are listed, notably, lactic acid is not mentioned.<sup>16</sup>

In short, the cited primary references belie the Examiner’s assertion that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute crystalline lactic acid for lactic acid. In fact, the references teach the opposite, which undermines the alleged determination of obviousness.

The MPEP uses the following example below to illustrate an improper combination of references. Because the illustration bears directly on the current facts, the example is reproduced below in its entirety:

Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).

Similarly, here, the prior art taught that crystalline lactic acid is “impossible” to encapsulate. Hence, a reference teaching encapsulation of “conventional” lactic acid combined with a reference teaching crystalline lactic acid would not suggest encapsulation of

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<sup>14</sup> Wu at col. 4, lines 54 – 56.

<sup>15</sup> Chung at 4, lines 1 – 8.

<sup>16</sup> *Id.* at lines 9 – 14.

crystalline lactic acid, in light of the disclosures in the art that taught away from the invention. The Examiner offers no rationale to the contrary. For at least this reason, the Office has failed to provide a proper rationale to combine the cited references in a manner to arrive at the presently claimed invention.

**2. One Of Skill In The Art Would Not Have A Reasonable Expectation Of Success In Combining Chung, Wu, Or Percel With Borsook And Schouten**

Even if, *arguendo*, the cited combination of references is deemed proper, such a combination would not have lead a person of ordinary skill in the art to have a reasonable expectation of success in making the combination to arrive at the present invention. To the contrary, one of ordinary skill in the art would have found explicit disclosure, all of which teaches *away* from the inventive composition.

While “[o]bviousness does not require absolute predictability of success,” obviousness does require “a reasonable expectation of success.”<sup>17</sup> Further, “there can be little better evidence negating an expectation of success than actual reports of failure.”<sup>18</sup> Percel provides precisely this type of evidence, because it confirms that it had been “impossible” to use crystalline lactic acid in encapsulated form. Such demonstrated failures deprive one of skill in the art from enjoying any reasonable expectation of success and offer, at best, a mere hope for success.

The absence of a reasonable expectation of success is further underscored by the Examples of the cited references, none of which use crystalline lactic acid. As noted above,

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<sup>17</sup> *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

for example, while Wu lists four suitable organic acids are listed, lactic acid is notably absent from the listing.<sup>19</sup> Such evidence of record mitigates against any finding of a reasonable expectation of success.

Taken together, Appellants respectfully submit that neither Chung, Wu nor Percel teaches the use of *crystalline* lactic acid, but rather expressly teach away from its use. Hence, one of skill in the art simply would not have a reasonable expectation of success in modifying Chung, Percel, or Wu as argued by the Examiner, at least because the very references used to support the alleged *prima facie* case for obviousness either expressly and/or impliedly warn against the use of crystalline lactic acid in arriving at the claimed invention.

#### **B. The Claimed Invention Results In Unexpected Results**

“A *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties.”<sup>20</sup> In this case, Appellants have rebutted any *prima facie* case by showing unexpected results. Specifically, by using crystalline lactic acid, the present inventors have surprisingly succeeded in encapsulating lactic acid particles without the need for a substrate.<sup>21</sup> The heretofore art required the use of solid carriers to absorb liquid lactic acid.<sup>22</sup> However, the use of solid carriers limits the amount of lactic acid that can be encapsulated. Hence, the lactic acid content of the inventive particles can be higher than previously possible, and the

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<sup>18</sup> See, e.g., *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354, 65 USPQ.2d 1961, 1972 (Fed. Cir. 2003).

<sup>19</sup> Chung at 4, lines 9 – 14.

<sup>20</sup> See M.P.E.P. § 2144.09 (citing *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963)).

<sup>21</sup> Spec. at page 5, lines 17-20.

<sup>22</sup> See generally Wu.

activity of the lactic acid is not impaired by any substrate.<sup>23</sup> Furthermore, the encapsulated solid lactic acid particles according to the invention are easy to handle and are less expensive than encapsulated liquid lactic acid.<sup>24</sup> The success of the invention was not expected from the prior art and rebuts a *prima facie* case of obviousness.

### VIII. Conclusion

The rejection of claims 1-5, 7-16 and 18-27 under 35 U.S.C. § 103(a) as allegedly obvious over Chung, Wu, or Percel in view of Borsook and Schouten is untenable because a *prima facie* case of obviousness has not been established. Indeed, the prior art lacks a motivation to combine the cited references in a manner to arrive at the claimed invention, and the prior art belies any expectation of success. Even if a *prima facie* case of obviousness had been established, Appellants have rebutted that case by succeeding unexpectedly in encapsulating lactic acid particles in the absence of a substrate. Thus, Appellants request that the Honorable Board reverse the outstanding final rejections of the claims.

Respectfully submitted,

Date November 27, 2007

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<sup>23</sup> Spec. at page 5, lines 17-20.

<sup>24</sup> Spec. at page 5, lines 20-22; page 11, lines 1-5.

**CLAIMS APPENDIX**

1. (Previously presented) A composition comprising an encapsulated particle comprising crystalline lactic acid and a wetting agent.
2. (Original) The composition of Claim 1 wherein the crystalline lactic acid particle comprises crystalline L(+)lactic acid.
3. (Original) The composition of Claim 1 wherein the crystalline lactic acid particle is encapsulated within a food-grade coating material comprising oil, fat, wax, carbohydrate, protein, polymer, or a mixture thereof.
4. (Original) The composition of Claim 3 wherein the food-grade coating material has a melting point between about 35 and 90C.
5. (Original) The composition of Claim 1, wherein the food-grade coating material is a vegetable oil.
6. (Canceled)
7. (Previously presented) The composition of Claim 1 wherein the wetting agent is silica, starch, calcium lactate, methyl cellulose, or a combination thereof.
8. (Previously presented) The composition of Claim 1 further comprising silica powder as the wetting agent and a partially hydrogenated fraction of a palm oil melting at 61C as an encapsulating coating.
9. (Original) The composition of Claim 1 wherein the encapsulated particle comprises up to 95%(w/w) lactic acid based on the total weight of the encapsulated particle.

10. (Original) The composition of Claim 8 wherein the coating material or coating material plus wetting agent represents about 5 to 70%(w/w) of the encapsulated particle.
11. (Original) The composition of Claim 8 wherein the coating material or coating material plus wetting agent represents about 30 to 60%(w/w) of the encapsulated particle.
12. (Original) The composition of Claim 1 wherein, upon dispersion in water at room temperature, less than 10%(w/w) of the lactic acid is released into the water after 60 minutes.
13. (Original) A food product composition comprising the encapsulated crystalline lactic acid particle of Claim 1.
14. (Original) The food product composition of Claim 13 wherein the food product comprises a comminuted meat product, a bakery product, or an acid-sanded candy.
15. (Previously presented) A method of preparing a food product comprising adding encapsulated crystalline lactic acid particles comprising crystalline lactic acid and a wetting agent to the food product whereby the color, flavor, or shelf-life of the food product is enhanced compared to a similar food product prepared without adding lactic acid.
16. (Original) The method of Claim 15 wherein the food product comprises a comminuted meat product, a bakery product, or an acid-sanded candy.
17. (Withdrawn) The method of Claim 15 comprising the acid-sanding of candies wherein the candies are acid-sanded with encapsulated crystalline lactic acid particles.
18. (Previously presented) A method of preparing encapsulated crystalline lactic acid particles comprising:
  - preparing crystals of lactic acid;
  - treating the crystals with a wetting agent prior to or during encapsulation; and
  - coating the crystals with an encapsulating coating material.

19. (Original) The method of Claim 18 wherein the lactic acid crystals are about 200 to 800 microns in size.
20. (Original) The method of Claim 18 wherein the lactic acid crystals are encapsulated using a top-spray fluid bed coater.
21. (Previously presented) The method according to claim 18 wherein the wetting agent is silica, starch, calcium lactate, methyl cellulose, or a combination thereof.
22. (Previously presented) An encapsulated particle comprising crystalline lactic acid and a wetting agent.
23. (Previously presented) The encapsulated particle of claim 22 wherein the crystalline lactic acid particle comprises crystalline L(+)lactic acid.
24. (Previously presented) The encapsulated particle of claim 22 wherein the crystalline lactic acid particle is encapsulated within a food-grade coating material comprising oil, fat, wax, carbohydrate, protein, polymer, or a mixture thereof.
25. (Previously presented) The encapsulated particle composition of claim 24 wherein the food-grade coating material has a melting point between about 35 and 90 °C.
26. (Previously presented) The encapsulated particle of claim 22, wherein the food grade coating material is a vegetable oil.
27. (Previously presented) The encapsulated particle of claim 22, wherein the wetting agent is silica, starch, calcium lactate, methyl cellulose, or a combination thereof.

**EVIDENCE APPENDIX**

The references cited herein were introduced into the record and entered during prosecution. Specifically, the only evidence discussed herein are the references forming the basis of the appealed rejection, which were cited in the Office Action mailed November 17, 2006.

**RELATED PROCEEDINGS APPENDIX**

Appellants are not aware of any related appeals or interferences, so Appellants have no information regarding related proceedings to submit.